Recordati S.p.A.

"2019 First Nine Months Results Conference Call"

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OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Recordati 2019 First Nine Months Results Conference Call. After the presentation, there will be an opportunity to ask questions.

At this time, I would like to turn the conference over to Ms. Marianne Tatschke, Director of Investor Relations and Corporate Communications of Recordati. Please go ahead, madam.

MARIANNE TATSCHKE: Good afternoon or good morning to everyone, and thank you for attending the Recordati conference call. Here with me today are Andrea Recordati and Fritz Squindo who will be presenting and commenting upon our first 9 months 2019 results. For a better understanding of this presentation, please access the set of slides available on our website www.recordati.com under the Investor section and presentations tab. At the end of the presentation, we will answer any questions you may have. Please go ahead, Andrea.

ANDREA RECORDATI: Thank you very much, Marianne. Good afternoon or good morning to everyone. I can start by saying that we are very pleased with our first 9 months results which show continued growth. Consolidated revenue is up to €1.1 billion and which is about 8.6% above last year, and includes sales generated by Natural Point, which was consolidated from July…3rd July 2018 of 9.7 million which are the sales generated by….sorry this is the Natural Point sales. Also by the sales generated by Tonipharm, which was acquired at the end of 2018 and consolidated from 1st of January 2019, of 18.8 million and sales of Juxtapid, which we acquired the license in February 2019 in Japan with €6.9 million sales, in addition to an estimated negative currency exchange rate of 3.4…FX of €3.1 million. Excluding these items, growth would have been of 5.4% on the previous year.

EBITDA at 37.6% of sales is at €409.6 million, up 7.8% on last year. Operating income is at 32.1% of sales at €353.5 million, an increase of 4.9% over last year. Net income is at 23.1% of sales and is at €253.7 million, an increase of 6.6% over the same period of last year.

Net debt is at €498.7 million compared to a net debt of €588.4 million at 31st December 2018. During this period, the period dividends were distributed for an amount of €96.1 million. An amount of €30 million was paid for the license agreement from Aegerion Pharmaceuticals for Juxtapid in Japan, and €40 million were paid to have milestones to Helsinn for the license agreement of Ledaga. Furthermore, the application of IFRS 16 gave rise to medium and long term debt of €25.9 million.

Regarding our corporate development activities during the period, the license agreement was signed with Helsinn for the exclusive commercialization of Ledaga and with Aegerion for Juxtapid in Japan. This is very important especially both rather, are very **i**mportant for us but Juxtapid has picked very well with our entry into Japanese market, has given a critical mass and it is very…therefore, very important for the development of this recently established subsidiary for our [indiscernible] business.

Companies operating under the name of the Orphan Europe have been renamed to Recordati Rare Diseases in order to kind of create a global brand for this franchise. Most recently, on October 23rd of this month, we finally closed the acquisition with Novartis for the worldwide rights to Signifor, Signifor LAR and for the treatment of Cushing's disease and acromegaly and also for obviously, the rights of osilodrostat. And so we are very excited about this and obviously we are moving on with the execution of the integration and this ramp up, but to get ready to somehow distribute this product worldwide and launch osilodrostat when this will be

approved. It is obviously very strategic…a significant strategic transaction for Recordati and we are as I said, very excited about it.

So let's move to the next slide, Slide 3 where we represent the same slides that were actually utilized in the analyst call at the end of July 2019 just to kind of recap on the key highlights of the Novartis endocrinology franchise acquisition. So the key highlights are obviously it's complementary to our portfolio. We enter into the high growth endocrinology market. These are orphan-designated drugs. They have good IP protection, they require limited additional R&D spend and have global and perpetual intellectual property rights. More specifically, regarding Signifor, it has IP protection until 2026, estimated around $75 million of revenues in 2019 with above average EBITDA margins and with peak potential sales of $100 million. And it's an orphan drug designation in the U.S. and Europe.

Regarding LCI699, osilodrostat, it has IP protection until 2031, marketing authorization applications have been filed in European Union and the USA with potential approval expected in 2020 in Europe and 2022 in the U.S. at the latest. Orphan drug designation in the Western Europe and we expect potential peak sales of above 100 million.

Moving on to the next slide just to recap the transaction snapshot. The deal purchase price required an upfront cash consideration of $390 million and it will also imply regulatory milestones in addition to royalties on net sales contingent upon approval and market access of osilodrostat. The funding was funded by existing liquidity and new debt facilities obtained in July. We believe this as an acceptable pro forma net debt to EBITDA level leverage leaving room for additional future M&A. And the timing as I mentioned previously, the closing took place on the October 23rd 2019.

So I will leave the floor to Fritz who will actually take you through the first 9 months results of the company.

FRITZ SQUINDO: Thank you, Andrea. Good afternoon or good morning to everyone. More in detail in our Page 5, and starting with the comment of our main product sales and let me say that we have the performance of our corporate products in line with our expectations. It's usually starting with the performance of lercanidipine and Zanidip sales are up by 6.9% thanks to the repatriation of license rights in some countries, but also thanks to the increase of the sales in China, Australia and in Central and Eastern European markets and we continue to have a good performance from our proprietary product lercanidipine.

So regarding the combination of the sales of Zanipress which is the combination between lercanidipine and enalapril, then the sales are down due to competition of the generic version as expected in the first now decreased by 3.3%. Now this is a very positive performance and we expect in particular thanks to the performance in this. In the last quarter, the sales have to be essentially stabilized. Urorec or silodosin sales are growing and are up about 8.6% and this is due to the good performance of the product in all the main markets.

Sales of Livazo, the brand of the pitavastatin grew by 16.3% and here again this is due to the good performance of the product in all the main markets and in particular in Turkey, Russia and in Spain. Then here our corporate Seloken is essentially stable a bit better than was the performance in the first six months.

Going then to the other corporate product, other corporate products are up by 13.3% and included the initial launches trades of Reagila, the new treatment for the schizophrenia. These lines…this group of products

include 23 products which are sold in multiple territories, 8 of which are OTC products, among these OTC product worth mentioning the continued very good performance of Procto-Glyvenol in all the Central and Eastern European market.

Then our specialties which I indicated for the treatment of rare diseases generated sales of €177.1 million during the period which an increase of 8.7% despite the competition from a generic version of Cosmegen in the United States, then also for rare disease we continue our trend of growing our sales.

We can now move on Slide 6, in which we present the breakdown of our revenue by type of products, just again to underline that our corporate products including also rare diseases account for 67.6% of our revenue. We are progressively building a portfolio which is a multi-territorial portfolio in our company.

In Slide #7…this slide shows sales performance by geography. And let me underline that we have a positive performance in all the country except North Africa in which we are impacted on some limitation of importation in Algeria, but overall a very good performance in all our territories.

Sales in Italy are up by 7.1%, EMEA is worth mentioning the good performance of Urorec, Cardicor, as well the sales of Natural Point, in particular Magnesio Supremo which is the most important brand of this company. The company we have acquired in June 2018. And in particular Magnesio Supremo sales are growing. Thanks to the management of Magnesio Supremo by our commercial organization.

Pharmaceutical sales in France are up by 19.3%, and this includes the addition of the product as Andrea said of Ginkor and the portfolio of

Tonipharm in particular, the 2 most important brands which are Ginkor and Alodont. We have acquired this company at the end of last year.

In Germany sales are substantially unchanged compared with those of the same period of the preceding year. But here, I would like to underline sales of Reagila the new drug for the treatment of schizophrenia, which has been launched in 2019, which is doing a good performance in Germany.

Revenue generated in Russia, Ukraine and the other CIS countries is €83.6 million, which are up by 11.3% compared to the same period of the preceding year and include an estimated currency exchange gain then in the past it was more common to prevent losses in term exchange rate, but in this year we are benefiting from a positive exchange rate, which could be estimating €1.1 million. But even if we exclude this exchange rate sales in Russia, in local currency are up by 9.3%, and here I think it's worth mentioning the significant growth of all our product…corporate product you are talking about Urorec, Livazo, Procto-Glyvenol as I said before Zanidip and [indiscernible].

The business in the USA is only dedicated to the treatment of rare diseases. Sales in the first 9 months in the U.S. are in €78.3 million and are up by 4.4%, in local currency are up by 0.5%. The growth of the main product in particular Carbaglu and Cystadane has offset the reduction of sales of Cosmegen due as I said to the competition from a generic version.

Sales in Spain are €69.2 million are up by 7.4%, and this is an organic growth mainly due to the performance of all our most important product in the portfolio.

Sales in Turkey are up by 13.4% in euro and include a negative currency affect which could be estimated here in €9.3 million. But it's worth mentioning the performance in local currency and in local currency sales of our Turkey subsidiary grew by 32.3% and here again thanks to the good performance of all our corporate products, but as well as also some important local brands.

Regarding the other geography, I think it is worth mentioning the significant increase in sales in the other European countries which is mainly due to the growth of sales in Poland, Bulgaria, Czech Republic and Baltics which is linked to the good performance of metoprolol in particular in this market.

Then we have our international sales which are up by 1.3%, which is mainly due to the good performance of the treatment of rare diseases in the Rest of the World and particularly to the sales in Japan. Thanks to the new acquired products like Juxtapid. Then as I said at the beginning, a good performance in all the markets except North Africa.

Slide #8, this graph show the geographical breakdown of our pharmaceutical revenue and let me say that there is no changes compared what was the breakdown in the previous presentation.

Now, we can move on Slide 9, in which we can present more in detail our first 9 months result in terms of P&L. Sales, we have already analyzed our revenue from the period. More on to gross profit, gross profit is €771.3 million with a margin of 70.1% of sales, which is slightly lower compared to that of the same period of the preceding year which is due to the price and currency affect and a product mix.

Selling expenses increased by 9.3% which is a slight increase as a percentage…which as a percentage of revenue compared to the same period of preceding year, and this is due…this increase of our sales which is higher than our selling expenses which is higher than our sales, this is mainly driven by the marketing expenses for the launch of the Reagila, in the next phase of the Reagila we are investing in the product.

The new market…the commercial organizations in the Nordic countries, Benelux and Baltics we have decided to have our own commercial organization also in this part of Europe, and also to the initial reinforcement of the organization dedicated for the rare disease segment follow the addition of the new important product and also in particular as a initial phase of the reinforcement that we have to do for the launch of the 2 asset acquired from Novartis.

Then we have our R&D expenses, which are €91.6 million and are up by €15.3 million due to advancement of the new development program, but also to the amortization [ph] of the amount allocated to intangible assets following the acquisition of Natural Point and Tonipharm. And also the amortization of the upfront payment for the recently acquired licenses for the rare disease product Ledaga and Juxtapid. G&A expenses are up by 6.6%, but are slightly reduced as a percentage of sales.

Now, let me comment on our EBITDA. EBITDA at 37.2% of sales is in the period €409.6 million with an increase of €7.8 million. In term of amortization charges, the amortization charges from the period are €37.8 million and this…with an increase which is due as I said of the intangible of the asset we have acquired in the last period. But we have also our depreciation charges which are increasing and are for the period €18.3 million and include the application of new accounting principles IFRS 16.

Net financial charges are essentially in line. We have…our net debt financial charges are €16 million and this increase of 2.2 is mainly due to the recognition and P&L of the fair value of a 2 cross currency swaps following the early termination of one loan in the U.S. market. The effective tax rate during the period is 24.8% lower than that of the preceding year and we are slightly reducing our tax rate.

And then let me again finish presenting our net income. Net income at 23.1% as a percentage of sales is €253.7 million and we have an increase in our net income an increase of 6.6%, which is very positive performance.

Then we can move on Slide #10. This slide show the split of revenues, EBITDA and EBIT between our 2 business segments, then the EBITDA margin are 49.6% for the rare disease segment and 34.9% for the specialty & primary care segment. EBIT margin are 45.5%, for the rare disease segments 29.6% for the specialty & primary care. Regarding the EBIT margin there is a slight reduction, which is for both the 2 business for the rare disease segment and the specialty & primary care segment.

#11 is the slide in which we present our net financial position, and net financial position has been presented by Andrea at the beginning show a net debt or €498.7 million compared to net debt at the end of last year of €588.4 million And then we have reduced our net financial position in the period by €89.7 million, but it's worth mentioning that during the period we have paid dividend by €96.9 million and we have also paid U.S. $13 for the license agreement with Aegerion and we have paid €40 for the milestone that we have paid to having for the license of the drug.

Then as Andrea said, there is also a negative impact in our debt following the application of the new IFRS 16. We have generated a long…medium,

long term liability of €25.9 million excluding all these items it was again mentioned that we continue to generate a very strong cash flow in this period.

Now, we can move on the last slide in which we as usual we present our target, and based on group performance in the first 9 months, we confirm our revenue and margin targets. Then we have a revenue target between €1,460 million and €1,480 million, which is the same that we have announced, the EBITDA between €535 and €545 million. Then we have an EBITDA margin expected as a target to be between €460 million and €470 million and our net income between €330 million and €335 million.

Then here I finished my presentation. Thank you for your attention. And now, we are available for any questions we may have. Please go ahead.

MARIANNE TATSCHKE: Operator, could you please open the question and answer section.

Q&A

OPERATOR: Excuse me. This is the Chorus Call conference operator. We will now begin the question and answer session. The first question is from Chris Ryan of Bank of America. Please go ahead.

CHRIS RYAN: Hi good afternoon. Thank you for taking my questions. My first question is just on the CFO role change. Could you give more detail on that and you know, in what ways is the business becoming more complex? And then the second question is, what right now are the approval expectations for the osilodrostat drug? Thank you.

ANDREA RECORDATI: Okay. So here we go. Thank you for your questions, Chris. So the first question regarding the CFO, this is a simply reinforcements of the

organization. The company is growing, is becoming more complex and we felt that we needed to or I felt that I needed to reinforce to the top management team of a group to better support this growth and the new complexities that we need to manage being the company larger and with obviously very ambitious growth expectations. So what we…obviously in agreement with Fritz Squindo. We started to look for which I would like to remind everybody was not only acting as CFO, but was also Managing Director of the company, and as always supported myself and the top-management team on anything that goes from business development strategy and evaluating new business opportunities and so forth.

So and he will keep…and remain in following this role on my side. But we…as I said, we felt that we needed to reinforce the organization. So we started looking around through, you know very structure and formal recruiting process and we came across candidate Mr. Luigi La Corte which…we felt ticked all the boxes due to his international experience and established experience also in the pharmaceutical industry with blue chip companies such as GSK and AstraZeneca not only in Italy but also in the international level [ph].

If that…hopefully that answers your question Chris?

CHRIS RYAN: Yes, I mean is there any change in financing strategy, could you say going forward versus how you know, the company is typically been capitalized?

ANDREA RECORDATI: No, nothing changes from the perspective, okay?

CHRIS RYAN: Okay.

ANDREA RECORDATI: Okay. So moving on to your next question, so I will divide it by U.S. and Europe, okay. Because, obviously, they follow different processes. So the

European commission formal approval is expected in Q1, 2020, okay. This will be followed by the market access process, country-by-country like it is normal in Europe. So we can expect a gradual launch, rollout starting in 2020 across different countries in Europe, and obviously…and beyond as we gain reimbursement status in the different markets. So that covers Europe for osilodrostat.

Regarding the USA, in our Business Plan, we have cautiously assumed the launch in the USA in 2022, okay. This was due to the lack of clarity and as to whether the FDA will require us to submit the link for study clinical data which is still an ongoing study that on the product which is been managed by Novartis. This is relevant, the clinical study report for this study, should they required, is expected in Q3, Q4 2020 which then will imply a launch and Q4 2021, Q1 2022. However, as I am sure some of you are aware we have a PDUFA date in March 2020 of next year. And so, we feel that we might have more visibility on the actual FDA requirement regarding the necessity of submitting the date of link for study at that time, and therefore the final launch timing.

CHRIS RYAN: Can I squeeze in one more, just do you…can you give the split between the expected sales between the U.S. and Europe?

ANDREA RECORDATI: We don't tend to disclose that sort of information especially on a product which has not even been launched yet. So we expect big potential sales to be above $100 million worldwide, but at this moment in time, we are not disclosing any more details on this.

CHRIS RYAN: Understood. Got it. Thank you.

ANDREA RECORDATI: Okay. Thank you, Chris.

OPERATOR: The next question is from Dominic Lunn of Credit Suisse. Please go ahead.

JO WALTON: Hello, Jo Walton from Credit Suisse. I've just got a few questions, please. As you move more into the specialty products, I guess, we are going to focus more on that performance. So I wonder if you could tell us a little bit more about how Reagila, for example, is doing Juxtapid. Just give us some sense of how you are being able to build up like the specialty infrastructure there? Could you also give us a little bit more as to why you think you will be able to grow the Signifor and Signifor LAR franchise, it's been around for a while. It hasn't been growing that fast and yet you think you can expand that in an increasingly competitive market. Is it that you have spotted a doctor, so you think would use the product who haven't been detailed about it or why do you think you continue to be able to get some growth? And my final question at least in this round would be to try and get a sense of what you think your R&D spend will be in the next year or so. And I know that a lot of your R&D expense is actually taken up with the charge for the amortization of intangible assets. So actually the cash research spend on new products is really still quite limited. Could you share with us some of your ambition is to where you would like that sort of cash R&D spend to be in a couple of years' time? Many thanks.

ANDREA RECORDATI: Hello Jo. I thought it was bit weird that you were not on the call. And so, let me start with…if I understood correctly you kind of went a bit quick there, Juxtapid, Japan and how the product is performing.

JO WALTON: And just the infrastructure that we have created.

ANDREA RECORDATI: And the infrastructure that we've created. Juxtapid…but you mentioned…you did mention Juxtapid in Japan…as an example? Okay.

Well, obviously Juxtapid, Japan we had already set up the organization and we reinforced based on the new targets that we had divested because…and Juxtapid implied an expansion of a target to be visited by our ODS or Orphan Drug Specialist in Japanese market. I can tell you that our product is actually performing beyond our expectations or in line just above our expectation so we are very pleased with this.

Going to instead the…I guess, the…your question is more around endocrinology and what we are doing to set-up ourselves to obviously take on these products and make them a success, because we were saying that obviously we did not have a private presence in endocrinology until now. So we are in the process of reinforcing the organization both on a worldwide level by creating obviously depending on the market, some markets require more dedicated endocrinology. So the business unit, see for example the U.S. where we are also smaller compared to Europe with our reach to the market in the first place. So this is what is going on the U.S.

We are setting up a specialized dedicated BU around the endocrinology franchise, and we're recruiting people with specific expertise and competence around this area. And in Europe, we are obviously recruiting people with endocrinology experience both on the field to reinforce ourselves where we need to reinforce ourselves, but also, let's say at the corporate level in order to bring expertise around this area. This goes for medical, regulatory, to strategic marketing and operational marketing. So we are moving and we are obviously very much aware that we do not have this expertise in-house. But we have the opportunity to actually at this moment in time to actually gain a lot of expertise from the outside. So we're actually on track on that and we are very satisfied of how we are progressing on this front. The other question was…?

JO WALTON: Yes, how can we continue to grow it…

ANDREA RECORDATI: Okay, you know, but that's a simple answer. Novartis had abandoned the promotion of this product for some time. More recently, in Europe for I'd say more than a year, but in the U.S. now, we're probably approaching nearly 3 years on non-promotion of the asset. So we believe, especially like you mentioned in a competitive scenario, that we…these products are present, that obviously this lack of promotion, but I'm talking about complete lack of promotion obviously has an impact on the performance of the products, which however are extremely still appreciated by the physician community and are still seen as a key element in the treatment of these diseases.

So we believe that, by putting this product back into promotion with the necessary investments and promotional spend and share of voice, we believe that we can definitely start putting this product back on a growth trajectory. The last question…I hope that answers your question. The last question was regarding R&D and I will let Fritz give you answer on that one.

FRITZ SQUINDO: Okay. Then regarding our R&D, the question was related to a target in terms of the cash part of these R&D expenses. This as you know, include also the amortization charges for the asset that we have bought. Let's say that is usual, R&D expenditure, in particular this cash part, is mainly driven by our program rather than as a specific objective as a percentage of sales. And then I cannot give you a target in terms of…cost in term as a percentage of sales. I can comment on this, what we expect…we expect also this part of the R&D going forward to increase. We expect for sure the amortization charges to increase the base of the amortization of the Novartis asset, but also the cash part we expect to increase driven by both the current advancement of the new development program, which are

moving progressively in term of development phase in our pipeline, but also to the cost, which are linked to the development and the reinforcement of the new assets that we have acquired from Novartis. Then overall, as a general comment, we expect this cost to increase going forward, also in the cash part.

JO WALTON: Thank you. And in case you're handing over your Investor Relations responsibilities to the new CFO, may I thank you for all of the calls that you've done for us in the past.

FRITZ SQUINDO: Okay. Thank you. Thank you.

ANDREA RECORDATI: Jo, you'll still be seeing Fritz, don't worry.

FRITZ SQUINDO: I will continue to be present.

OPERATOR: The next question is from Bruno Permutti of Banca IMI. Please go ahead.

BRUNO PERMUTTI: Okay. Good afternoon. A few questions. The first one, if you can give us an indication of the organic growth of the first 9 months and if 4% organic growth you see is a sustainable rate for 2020, 2021. And second one was on Reagila, if you can give us an indication of the amount of sales in the 9 months. And the last one is on the distribution network organization. I don't know if I have well understood, you had an early organization in Northern Europe. I want to understand what you imagine for the future, if you have some other changes that you are playing in the distribution network and if you have some costs related to this and also benefits you expect for the next years.

FRITZ SQUINDO: Okay. The first question was in the organic growth, the organic growth in the period, as Recordati said in the presentation, was 5.4%, if we exclude

contribution from the acquisition and also the negative FX impact. This is a very solid performance, which is a line, a bit better, that was included in our…in our Business Plan. But we have announced a CAGR [ph] in terms of…in our Business Plan in term of organic growth. And what we expect in 2020, probably this growth will be lower because we have to face the generic competition of Urorec and Pitavastatin and then going forward we expect in '21 to start again to grow probably to the level that we have achieved in 2000…we are achieving now in the first 9 months and we expect to achieve during the full-year 2019.

Reagila sales in the first 9 months are around €5 million, which means that we continue to start growing the business. It's important to say that now we have the addition of 2 new important markets in which we have now launched the drug, these are Spain and Portugal in which we have a solid presence. And then we continue to believe that Reagila is a very good product with a delay in terms of uptake driven mainly by a more complex market access than what was expected, not in term of price reimbursement, but in some markets it is very important for this type of product also going to use in the different formula. Then…?

MARIANNE TATSCHKE: And distribution network organization in Northern Europe, if you're going to do more of that.

ANDREA RECORDATI: No, in Northern Europe.

FRITZ SQUINDO: No, we have now established our own presence in these markets, thanks to the repatriation of some of our corporate products and in particular thanks to the metoprolol sales, and now these with our subsidiaries, which we expect to develop in line with all the other parts of our business.

MARIANNE TATSCHKE: Any changes in the future?

ANDREA RECORDATI: No, regarding our commercial organization…was the question regarding commercial organizations?

BRUNO PERMUTTI: Yes. Yes, correct.

ANDREA RECORDATI: Well, as said, there obviously the changes are in places based around any additional M&A activity, business development activities that might come in the future. So at the moment…this moment in time, we're not planning to reinforce the commercial organizations in this area.

MARIANNE TATSCHKE: For the Specialty and Primary Care.

ANDREA RECORDATI: For the Specialty and Primary Care. Obviously, for the endocrinology, I went through it extensively in the previous question, as well.

BRUNO PERMUTTI: Thank you.

ANDREA RECORDATI: You're welcome.

OPERATOR: The next question is from Isacco Brambilla of Mediobanca. Please go ahead.

ISACCO BRAMBILLA: Good evening, everybody. And thanks for taking my question. I have seen actually, the first one is on organic growth, if my calculation is correct you posted high single-digit organic growth in the third quarter. So, I was wondering whether there was some kind of phasing, in some countries affecting this performance. And if it is not the case, whether we should assume in organic growth in full year ’19 a touch above the usual [indiscernible] by the Business Plan in the regional of 4.5%.

Second question is on your 2021 target on EBIT margin. Is this, is the target of 33% still valid and if it is the case, when we should see, we should expect to see some kind of inflection point on the trajectory of EBIT margin which has been eroding in the past three, four quarters. And the last question is on net debt, where do you see it by the end of 2019, I acknowledge that you have no guidance on this, but I see on Bloomberg, a consensus in the region of €900 million including the cash out of Juxtapid and I was wondering whether this number give you confidence to deliver expectation?

FRITZ SQUINDO: Okay. Then, the first question was linked to the organic growth in the third quarter. Is it correct?

ISACCO BRAMBILLA: Yes.

FRITZ SQUINDO: In this quarter. Okay, then, okay in this quarter, we have a very solid organic growth which is driven by all our portfolio, but as usual, we don't believe one quarter is something that could be extrapolated as a long-term trend. And then we confirm that for us, it's more in line with our expectation what we have achieved for the full 9 months. We are very pleased by this 5.4% organic growth and this is what you could expect for the full year.

Regarding our objective in terms of EBIT margin then, we…for sure, we will release a new Business Plan next year probably in May, then we…but for the time being, for sure we confirm our EBIT margin. Then, you will see now a slight reduction of this EBIT margin, which is mainly driven by the type of acquisition we are now closing, we are now closing acquisition in which there are important assets, important amortization charges and also we are in the initial phase of the launch of osilodrostat and with

launches of Signifor, Signifor LAR which required reinforcement and not are immediately accretive in terms of EBIT margin.

We expect to be essentially inline in terms of EBITDA margin, but EBIT margin not necessary accretive. But, this we expect to be the impact in the first period and then today, we confirm our margin which as you know, include also an acquisition for 2021, no changes for…regarding our target in our Business Plan. Regarding net debt, yes, we are absolutely confident with the number that is in the consensus of Bloomberg, when we expect our net debt to be around €900 million at the end of the year.

ISACCO BRAMBILLA: Very clear. Many thanks.

FRITZ SQUINDO: Bye.

OPERATOR: The next question is from Giorgio Tavolini of Intermonte. Please go ahead.

GIORGIO TAVOLINI: Hi, good afternoon. And thank you for taking my question. I would like to ask you what's behind the pharmaceutical chemical sales that in the third quarter for the first time had a 10.4 drop year-over-year. Thank you.

FRITZ SQUINDO: Okay. Here again…then we prefer to comment the overall performance. This is one business, which is supplying to other pharmaceutical company and sometimes stock building and stock the orders, stocking of this company has an impact in the quarter. Then no concern, then we believe that you have to keep as a base for the evaluation of the performance of this business, the performance in the…in the 5…in the 9 months result. Then, we don't believe in particular for phasing effect...phasing effect are nothing which is significant for the business.

GIORGIO TAVOLINI: Okay. Thank you.

FRITZ SQUINDO: Bye.

OPERATOR: The next question is a follow-up from Dominic Lunn of Credit Suisse. Please go ahead.

ANDREA RECORDATI: Hello Jo.

JO WALTON: Hi, hello, just 3 quick ones. Given that you have produce date for osilodrostat for next year, if you had any indication as to whether they are actively considering this and perhaps giving you an ad com [ph], or you know, so I would expect you to have an idea before March as to whether the FDA actually requires the additional data or not. Have you managed to bring on board any of the people with an intimate knowledge of these products from Novartis or are you taking just the products with absolutely no people from it. And could you also give us an update on the Carbaglu generics, you were suffering from the genericization there. Sorry, and what level of erosion you've got to with the generics, did you…has it all gone, has it reached a stable level, how should we think about business going forwards, sorry I mean [multiple speakers].

FRITZ SQUINDO: Okay. Thank you….

JO WALTON: I was going to ask you about the progress for expanding the indication for Carbaglu?

ANDREA RECORDATI: Okay. So, first question, so regarding endocrinology, recruiting of people, I will start with the second one. I can tell you that obviously it was so implicit in the explanation, I guess, it wasn't very implicit that the recruitment is…we are recruiting an organization with people that

obviously have been expertise around this area and obviously some of these people are coming from Novartis, because obviously, they divested the business and so there is a bit of movement on that front. So, this is obviously an opportunity that we could have made there and we are pursuing it.

The first…sorry the first question you said was…the PDUFA date…the PDUFA date giving you, I mean possibly it's a bit, it's a bit difficult to say, Jo, I mean we might have some feedback before the March 2020 PDUFA date from the FDA, but we are not…we are not counting on it 100%. So…but sure at the PDUFA date time, we will have a full visibility if this link is required it's not, okay. Last but not least Cosmogen is close to steady state and basically it is obviously being impacted like we have already declared by the generic penetration, but not beyond, extensively beyond what we were expecting.

JO WALTON: Thank you.

ANDREA RECORDATI: Okay. You are welcome.

OPERATOR: Mr. Recordati, there are no more questions registered at this time.

ANDREA RECORDATI: Okay. Thank you very, very much for your time and for your questions and have a good evening or a good day depending on where you are. Thank you. Okay, bye-bye.

FRITZ SQUINDO: Bye-bye.